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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,316

03/17/2006

Robert Jongejan

27233U

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34375 7590 12/21/2010

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

12/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,316	Applicant(s) JONGEJAN ET AL.	
	Examiner Danton DeMille	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Applicant's arguments in the Appeal Brief of 27 August 2010 have been found persuasive. New references have been found and therefore the previous office action has been withdrawn. The examiner apologizes for any inconvenience this may cause.

Claim Rejections - 35 USC § 112

Claims 2, 5-7, 9, 11, 12, 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2, it is not clear what structural limitation is comprehended the language where the monitor does not affect the normal operation of the drug delivery device. The drug delivery device is not part of the claimed combination. Therefore it is not clear how one is to infringe this claim without the drug delivery device present. Different drug delivery devices may affect the interaction between the monitor and the drug delivery device. What structural limitation of the monitor does this claim further limit?

Claims 5-7, 9, 25 further describe the drug delivery device however, as noted above, the drug delivery device is not part of the claimed combination and therefore what the drug delivery device is or its relative position does not further limit the claimed invention.

Moreover, claim 5 further limits the invention in claim 1 by stating that the proper positioning of the drug delivery device is positioned in contact with or relative to the user's mouth, nose or skin. Claim 1 has already recites a temperature sensor for sensing body

temperature when it enters or contacts the user's mouth. It would appear that claim 5 is outside the scope of claim 1.

Claim 1 has already recited a sensor for sensing the proximity to the user and claims 11 and 12 add an additional light sensor and conductivity sensor to the temperature sensor already claimed. There appears to be no support in the specification for the combination of a temperature sensor with a light and conductivity sensor.

Claim Rejections - 35 USC § 103

Claims 1-9, 11-22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. (US 5,284,133) in view of Sprinkel, Jr. (US 5,261,424).

Burns teaches a compliance monitor for a drug delivery device with a mouthpiece comprising a switch 44, a "lip sensor arrangement includes a pair of spaced apart electrical contacts 76 at the mouth piece 14 which are connected to the controller 24 by wire 78. When the patient presses the contacts 76 together with his mouth during actuation, delivery of the drug to the patient is confirmed", column 12, lines 18-23. While the switch of Burns is a pressure switch, there appears to be no unobviousness to using other equivalent alternative switches that perform the same function. A conductivity switch or a light sensor or a temperature sensor would have been obvious equivalent alternative means for performing the same function.

Sprinkel teaches the use of a lip sensor for monitoring when the lips are placed on the tip of a flavor generator which then initiates heating of the flavor-generating material. Sprinkel teaches a piezoelectric sensor that can be used to detect the change in temperature that occurs when the flavor generator is placed between the user's lips, sentence spanning columns 2 and 3. It would have been obvious to one of ordinary skill in the art to modify Burns and use a temperature

sensor as taught by Sprinkel as an obvious equivalent means for detecting lips being placed upon a mouthpiece. Moreover, since applicant's own invention teaches that the proper position sensor can either be a light sensor or a conductivity sensor or a temperature sensor proves that there is no criticality to any one type of sensor. Any conventional type of sensor to detect body positioning can be used.

Regarding claim 3, Burns teaches the compliance monitor 24 can either integral with or connected to the medicated dose inhaler, column 8, lines 7-9. If the monitor is not integral then it is removable.

Regarding claim 4, Burns teaches a timer 26 that acts as a clock.

Regarding claims 11, and 12, light sensors and conductivity sensors are well known sensors for detecting human contact or proximity and such would have been an obvious alternative means for performing the same function.

Regarding claim 15, Burns teaches an input/output device 32 for downloading the information stored therewithin, column 8, lines 36-39.

Regarding claim 16, docking stations are old and well known and would have been an obvious equivalent means for downloading or uploading information into the system.

Regarding claim 17, Burns teaches using a remote computer that would have computer-readable medium for carrying computer program for programming to receive and process data downloaded from the monitor.

Regarding claim 19, Burns teaches the method of using the compliance monitor as claimed.

Art Unit: 3771

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974.

The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 December 2010

/Danton DeMille/

Danton DeMille
Primary Examiner
Art Unit 3771